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Attorney Docket No. MP/155

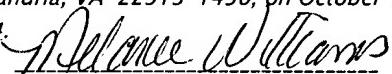
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Krall et al.  
Appl. No. : 09/848,121  
Filed : May 2, 2001  
Title : Defibrillation Electrode Cover  
Group Art Unit : 3762  
Examiner : Schaetzle, Kennedy

MS Appeal Brief - Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

BEFORE THE BOARD  
OF PATENT APPEALS  
AND INTERFERENCES

*I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on October 1, 2004.*

  
Melanee Williams

Melanee Williams

**LETTER OF TRANSMITTAL**

Dear Sir:

Applicants enclose the following papers for filing in the U. S. Patent and Trademark Office in connection with the above-identified Patent Application:

1. Three (3) Copies of Appeal Brief under 37 CFR 1.192 (4 pages each; 12 pages total).
2. Three (3) Copies of Appendix A Claims on Appeal (4 pages each; 12 pages total).
3. Three (3) Copies of Appendix B - Declaration Under 37 CFR 1.131 (2 pages each, 6 pages total)

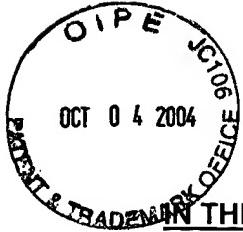
**The Commissioner is hereby authorized and requested to charge all fees due under section 1.17 during the pendency of this application to our Deposit Account No. 07-1729.**

Respectfully submitted,

  
Wayne D. House

Wayne D. House  
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Date: 1 OCT 2004



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PATENT & TRADEMARK OFFICE IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Melanee Williams

Melanee Williams

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Sir:

Three copies of this Brief are provided herewith.

**Applicants request that the fee for the Appeal Brief be taken from our Deposit Account No. 07-1729.**

This appeal is taken from the Office's final rejection mailed Feb. 3, 2004, and Advisory Action mailed 16 Aug. 2004, of claims 1-51. The Notice of Appeal was timely filed on Aug. 2, 2004.

Real Party in Interest

The above-referenced application names Robert C. Krall, Louis J. Smith and Peter J. Zeller as co-inventors. The application has been assigned to Gore Enterprise Holdings, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, Delaware 19714; a subsidiary of W. L. Gore & Associates, Inc., 550 Paper Mill Road, Newark, Delaware 19714. The assignment was recorded in the U.S. Patent and Trademark Office on August 27, 1999 at Reel: 010233 and Frame: 0897.

Related Appeals and Interferences

There are no other appeals or interference proceedings pending in the above-referenced application.

### Status of Claims

Claims 1-51 were originally filed in the above-referenced application. All of these claims are pending in the application and are the subject of the present appeal. Claim 47 is now canceled, as further described below.

### Status of Amendments

Independent claim 42 is amended herein by the addition of a further thickness limitation consistent with the thickness limitation of the other two independent claims (claims 1 and 22). As the thickness limitation now added to claim 42 is the same limitation of dependent claim 47, claim 47 is now canceled.

The amendment is made in the interest of putting all claims in condition for allowance.

Claim 42 (presently amended):

42. An implantable defibrillation lead, comprising:  
an electrode;  
a cover in contact with the electrode, said cover comprised of a porous polymer;  
wherein the porous polymeric cover has a thickness less than about 0.13mm; and  
wherein the cover is non-conductive in a dry state and provides rapid re-wetting following a transmission of a series of electrical discharges.

Claim 47 (canceled).

### Summary of the Invention

The present invention relates to an implantable electrode provided with a thin, porous, wettable polymeric covering. The electrode covering of the present invention tightly conforms to the external profile of an electrode, which minimizes air gaps and voids. The electrode covering is relatively thin, less than about 0.13 mm thick, and is treated to enhance rapid wetting by bodily fluids. The combination of minimal air gaps, tight conformance to the electrode, wettability and porosity of the thin covering, allows repeated, high energy electrical discharges to be transmitted without significant bubble formation, sparking or degradation of the covering. In addition, the electrode covering of the present invention has pore sizes tailored to minimize cellular ingrowth and tissue attachment thereby allowing a less traumatic removal of the electrode after

implantation if extraction becomes necessary, for example due to infection or electrode dislodgment.

Issue

All claims stand rejected over US Patent Application Publication No. 2002/014786 to Soukup et al. Specifically, claims 1-6, 8-12, 15-21, 42-47, 50 and 51 are rejected under 35 U.S.C. 102(e) as anticipated by this reference. Claim 7 is rejected as unpatentable over Soukup et al. under 35 U.S.C. 103(a). Claims 13, 14, 22-41, 48 and 49 are rejected under 35 U.S.C. 103(a) as unpatentable over Soukup et al. in view of Carson, US 5,931,862.

Applicants previously submitted 37 CFR 1.131 declarations from Robert C. Krall stating that the invention was made prior to the filing of the Soukup reference, on which all rejections are based. A subsequent declaration was filed by Dr. James D. Lewis verifying that the thickness of the electrode referred to in the original Krall declaration was actually as thin as required by the claim limitations.

The Office states in the Advisory Action mailed Aug. 16, 2004 that the claims remain finally rejected because the Applicants' paper of July 22, 2004 did not include a supplemental declaration under 37 CFR 1.131 from declarant Krall specifically referring to the Lewis statement as supporting evidence of the allegation of fact. The lack of the supplemental declaration from Mr. Krall appears to be the sole issue.

Grouping of Claims

In order to make the appeal process as efficient as possible, applicants request that the grounds for rejection be considered as three groups against, respectively, independent claims 1, 22 and 42. For the purposes of this appeal, the remaining dependent claims will stand or fall together with the particular independent claims from which they individually depend.

Argument

As noted above, the Office states in the Advisory Action mailed Aug. 16, 2004, that the claims remain finally rejected because the Applicants' paper of July 22, 2004 did not include a supplemental declaration under 37 CFR 1.131 from declarant Krall specifically referring to the Lewis statement as supporting evidence of the allegation of fact.

The requested declaration is submitted herewith. It was not submitted previously due to the temporary unavailability of Mr. Krall at the time of filing of the July 22, 2004 papers. It was concluded at that time that, because Dr. Lewis declaration identified the lead that he measured (by its serial number) as being the same lead described previously by declarant Krall (also

identified by the same serial number), that a further declaration by Mr. Krall would not be necessary. As the Examiner made reference in his Advisory Action mailed Aug. 16, 2004 to the lack of such a supplemental declaration from Mr. Krall, that supplemental declaration is submitted herewith. Because the description of the thickness of the electrode covering is the critical issue for all three independent claims (including claim 42 as amended herein), it is believed that the claims should now be in condition for allowance.

Accordingly, claims 1, 22 and 42 of the present application are not anticipated by either the published Soukup et al. application as Applicants have demonstrated by the declarations of Mr. Krall and Dr. Lewis that they were in possession of the claimed invention prior to the priority date of that reference. As all rejections are based on that reference, reversal of the rejections is respectfully requested.

Respectfully submitted,



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Date: 1 OCT. 2004

**APPENDIX A -- CLAIMS ON APPEAL**

1. An implantable defibrillation lead, comprising:  
a coiled defibrillation electrode;  
a cover at least partially surrounding the coiled electrode resulting in a covered electrode;  
the cover comprising a porous polymer;  
the cover being electrically non-conductive in a dry state and conductive when implanted to provide effective conduction of a defibrillation electrical charge; and  
the cover having a thickness of less than about 0.13 mm;  
wherein the cover provides a barrier to tissue attachment.
2. The lead of claim 1 wherein the cover has a thickness of less than about 0.10 mm.
3. The lead of claim 1 wherein the cover has a thickness of less than about 0.07 mm.
4. The lead of claim 1 wherein the cover has a thickness of less than about 0.05 mm.
5. The lead of claim 1 wherein the cover has a thickness of less than about 0.04 mm.
6. The lead of claim 1 wherein the cover has a thickness of less than about 0.03 mm.
7. The lead of claim 1 wherein the cover has a thickness of less than about 0.01 mm.
8. The lead of claim 1 wherein the porous polymer comprises PTFE.
9. The lead of claim 8 wherein the PTFE comprises porous expanded PTFE.
10. The lead of claim 9 wherein the ePTFE comprises multiple layers of ePTFE film.
11. The lead of claim 1 wherein when compared in a force-to-deflect test, a ratio of force-to-deflect of said covered electrode to the coiled electrode without cover is less than about 35:1.
12. The lead of claim 1 wherein when compared in a force-to-deflect test, a ratio of force-to-deflect of said covered electrode to the coiled electrode without cover is less than about 10:1.
13. The lead of claim 1 wherein said porous polymer cover is provided with a wetting agent.

14. The lead of claim 13 wherein said wetting agent comprises polyvinyl alcohol.
15. The lead of claim 1 wherein said lead is easily extracted from a body within which it has been implanted.
16. The lead of claim 1 wherein said cover exhibits no visually apparent mechanical disruption when viewed under 30X microscopy, following testing in a saline solution with a series of 20 biphasic single cycle voltage pulses.
17. The lead of claim 1 having a fatigue life of at least 1 million cycles.
18. The lead of claim 17 having a fatigue life of at least 5 million cycles.
19. The lead of claim 17 having a fatigue life of at least 100 million cycles.
20. The lead of claim 17 having a fatigue life of at least 400 million cycles.
21. The lead of claim 1 in combination with a pulse generator.
22. An implantable defibrillation lead, comprising:  
a coiled defibrillation electrode;  
a cover at least partially surrounding the coiled electrode;  
the cover comprising a porous polymer;  
the cover being provided with a treatment of a wetting agent; and  
the cover having a thickness of less than about 0.13 mm;  
wherein the cover provides a barrier to tissue attachment.
23. The lead of claim 22 wherein the cover has a thickness of less than about 0.10 mm.
24. The lead of claim 22 wherein the cover has a thickness of less than about 0.07 mm.
25. The lead of claim 22 wherein the cover has a thickness of less than about 0.05 mm.
26. The lead of claim 22 wherein the cover has a thickness of less than about 0.04 mm.

27. The lead of claim 22 wherein the cover has a thickness of less than about 0.03 mm.
28. The lead of claim 22 wherein the cover has a thickness of less than about 0.01 mm.
29. The lead of claim 22 wherein the porous polymer comprises PTFE.
30. The lead of claim 29 wherein the PTFE comprises porous expanded PTFE.
31. The lead of claim 30 wherein the ePTFE comprises multiple layers of ePTFE film.
32. The lead of claim 22 wherein when compared in a force-to-deflect test, a ratio of force-to-deflect of said covered electrode to the coiled electrode without cover is less than about 35:1.
33. The lead of claim 22 wherein when compared in a force-to-deflect test, a ratio of force-to-deflect of said covered electrode to the coiled electrode without cover is less than about 10:1.
34. The lead of claim 22 wherein said wetting agent comprises polyvinyl alcohol.
35. The lead of claim 22 wherein said lead is easily extracted from a body within which it has been implanted.
36. The lead of claim 22 wherein said cover exhibits no visually apparent mechanical disruption when viewed under 30X microscopy, following testing in a saline solution with a series of 20 biphasic single cycle voltage pulses.
37. The lead of claim 22 having a fatigue life of at least 1 million cycles.
38. The lead of claim 37 having a fatigue life of at least 5 million cycles.
39. The lead of claim 37 having a fatigue life of at least 100 million cycles.
40. The lead of claim 37 having a fatigue life of at least 400 million cycles.
41. The lead of claim 22 in combination with a pulse generator.

42. (Presently Amended) An implantable defibrillation lead, comprising:
  - an electrode;
  - a cover in contact with the electrode, said cover comprised of a porous polymer;  
wherein the porous polymeric cover has a thickness less than about 0.13mm; and  
wherein the cover is non-conductive in a dry state and provides rapid re-wetting following a transmission of a series of electrical discharges.
43. The lead of claim 42 wherein the cover provides a barrier to tissue attachment.
44. The lead of claim 42 wherein the porous polymer cover further comprises PTFE.
45. The lead of claim 44 wherein the PTFE comprises porous expanded PTFE.
46. The lead of claim 45 wherein the ePTFE comprises multiple layers of ePTFE film.
47. CANCELED
48. The lead of claim 42 wherein said porous polymer cover is provided with a wetting agent.
49. The lead of claim 48 wherein said wetting agent comprises polyvinyl alcohol.
50. The lead of claim 42 wherein said lead is easily extracted from a body within which it has been implanted.
51. The lead of claim 42 in combination with a pulse generator.

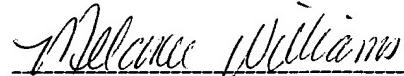
APPENDIX B -- DECLARATION OF ROBERT C. KRALL

Attorney Docket No: MP/155

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Melanee Williams

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION UNDER 37 CFR 1.131**

Dear Sir:

I, Robert C. Krall, am an inventor of the present application. On Nov. 20, 2003, I signed a declaration describing a coiled defibrillation electrode lead as taught by the present application. This prior declaration includes the necessary date information. Among other attributes of these inventive leads that I described in the previous declaration was the thickness of the electrode covering, which I stated to be about 0.023mm thick. The purpose of this declaration is to confirm that the covered electrode lead measured by Dr. James D. Lewis is the same lead, No. 7109104572, described by me in my previous declaration of Nov. 20, 2003. The photographs submitted with the previous declaration (Exhibits B1 and B2) are of this same lead, No. 7109104572. The uncovered lead that Dr. Lewis also measured is of the same type, and from the same supplier, as lead No. 7109104572. Both the covered and uncovered leads were taken from my lab notebook and supplied to Dr. Lewis for measurement, after which they were returned to the lab notebook. Dr. Lewis' measurements indicated that the thickness of the lead covering was 0.024mm. This supporting evidence is described in the declaration of Dr. Lewis, signed by him on July 21, 2004 and included with the response mailed on July 22, 2004.



RCK  
Oct. 1, 2004

The declarant further states that the above statements were made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statement may jeopardize the validity of this application or any patent resulting therefrom.

Date: Oct. 1, 2004

  
Robert C. Krall